NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEMPSEY EUGENE COOPER, Plaintiff, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	:	Civil Action No. 07-885 (FLW) **OPINION**

WOLFSON, District Judge:

Plaintiff Dempsey Eugene Cooper ("Plaintiff" or "Mr. Cooper") brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that he suffered injuries as a result of Defendants' design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Amended Complaint ("Amended Complaint") asserts various Alabama state and common law claims against Defendants, including Failure-to-Warn, Defective Design, Manufacturing Defect and Negligence.[1] Before the

[1] In his Original Complaint, Plaintiff initially asserted New Jersey state and common law claims against Defendants. Following two separate decisions rendered by the New Jersey Supreme Court in 2007, Plaintiff voluntarily dismissed those New Jersey claims and amended his Complaint to assert causes of action arising only under Alabama state law. See Opinion dated December 30, 2009,

Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under Alabama law. For the reasons that follow, Defendants' motion for summary judgment is GRANTED and all counts in the Amended Complaint are dismissed.[2]

BACKGROUND[3]

A. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food and Drug Administration ("FDA") for use as monotherapy, i.e., taken without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral vascular disease ("PVD"). See Defs. Statement, ¶ 2. Thereafter, the FDA approved Plavix for dual

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pp. 2-3. Therefore, Alabama law controls on this motion.

[2] Pending before this Court are related cases filed by other plaintiffs who were allegedly injured by ingesting Plavix, albeit their injuries may be different than those suffered by Mr. Cooper in this case. In those related cases, Defendants have also filed summary judgment motions. Moreover, the Court is aware that there are numerous cases concerning Plavix brought against Defendants in other state and federal courts across the country. Because each plaintiff's personal circumstances differ, the Court's findings in this Opinion only represent the application of pertinent state law, i.e., Alabama, to the facts presented in this particular case. That said, to avoid unnecessary duplication of effort in my several related cases and to conserve judicial resources, I cite to the analysis of similar legal issues in my published opinion in Solomon v. BMS, Civil Action No. 07-1102 (FLW) (Slip Op.), where appropriate.

[3] The following facts are undisputed unless otherwise noted.

therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").[4] Id. at ¶ 3.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, labeling on Plavix included certain information on that risk. The label provides:

> **PRECAUTIONS**
>
> **General**
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.
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> *GI Bleeding*: PLAVIX prolongs the bleeding time. In CAPRIE[5], PLAVIX was associated with a rate of

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[4] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not receive enough blood because of plaque narrowing or blocking of the arteries leading to the heart. Commonly, ACS includes, inter alia, heart attacks and irregular chest pains known as unstable angina. See, e.g., Frederick G. Kushner, et al., 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infraction and Guidelines on Percutaneous Coronary Intervention, 54 J. Am. C. Cardiology 2205, 2212 (2009).

[5] According to BMS, the clinical evidence for the risks of PLAVIX is derived from two double-blind trials: (i) the CAPRIE study (Clopidogrel v. Aspirin in Patients at Risk of Ischemic Events), a comparison of PLAVIX to aspirin, and (ii) the CURE study (Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events), a comparison of PLAVIX to placebo, both given in combination with aspirin and other standard therapy. See February 2002 Plavix Labeling, p.3. While Plaintiff contests the accuracy

> gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.
>
> * * *
>
> **Information for Patients**
> Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician.
>
> * * *
>
> **ADVERSE REACTIONS**
> *Hemorrhagic*: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.
>
> In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3)[6]. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), was the same in both groups.

See, generally, February 2002 Plavix Labeling.

B. Plaintiff's Medical History

Plaintiff, a 72-year old man, has a history of coronary artery

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of these clinical trials, its arguments are not relevant to my disposition of this case. They are addressed in detail, however, in my opinion in Solomon.

[6] Table 3 of the labeling includes certain "incidence of bleeding."

disease and acute coronary syndrome. In September 2004, when he was 64 years old, Mr. Cooper was diagnosed with severe diffuse multivessel coronary artery disease and unstable angina. See Disharge Summary, Flowers Hosp. (Tayes Cert., Ex. 43). Mr. Cooper underwent a left heart cardiac catheterization on September 1, 2004, and a coronary artery bypass grafting on September 2, 2004. Id. Following surgery, he was placed on Plavix by an unidentified doctor—likely a cardiologist—at Flowers Hospital. See Physician's Order Form (Tayes Cert., Exh. 44); Johnson Dep. 77:7-21.[7]

Thereafter, once Plaintiff was discharged, his primary care physician, Dr. Bruce Williams, kept Plaintiff on combination (or dual) Plavix/aspirin therapy, until February 22, 2005. See Insurance Statement at 1 (Tayes Cert., Exh. 46); Flowers Hosp. Medical History at 1 (Tayes Cert., Exh. 47). On that date, Plaintiff became dizzy in the middle of the night and was taken to Flowers Hospital by his wife. See Flowers Hosp. Medical History at 1 (Tayes Cert., Exh. 47). Plaintiff was subsequently diagnosed with a cerebellar hemorrhage, a type of stroke, and was ordered to stop taking Plavix. Id.

C. Plaintiff's Amended Complaint

[7] While Defendants state in their Statement of Material Facts that Dr. Stephen Johnson prescribed Plavix to Plaintiff, Mr. Johnson's deposition testimony makes clear that Defendants' statement is incorrect. See Johnson Dep. 77:7-21.

Due to the cerebellar hemorrhage allegedly resulting from taking Plavix, Plaintiff brings the instant suit against Defendants asserting product liability related causes of action for defective design, manufacturing defect, failure to warn, and negligence under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD")—Alabama's codification of its product liability law. See Am. Compl., Count I - Count IV.[8] Although these claims are characterized differently, they essentially turn on whether Defendants adequately warned that Plavix carried a risk of bleeding complications. In that regard, Defendants argue that the learned intermediary doctrine precludes Plaintiff from suing them because the doctrine excuses drug manufacturers from warning Plaintiff, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks. It is this issue upon which the Court will focus.

DISCUSSION

I. Standard of Review

Summary judgment is "proper if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." Pearson v. Component Tech. Corp., 247 F.3d

[8] On December 30, 2009, this Court dismissed Plaintiff's claims for negligent misrepresentation (Count V) and for violation of the Alabama Deceptive Trade Practices Act (Count VI). See Order dated December 30, 2009.

471, 482 n. 1 (3d Cir.2001) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)); accord Fed. R. Civ. P. 56(c). For an issue to be genuine, there must be "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party." Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir.2006); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether a genuine issue of material fact exists, the court must view the facts and all reasonable inferences drawn from those facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Curley v. Klem, 298 F.3d 271, 276-77 (3d Cir.2002). For a fact to be material, it must have the ability to "affect the outcome of the suit under governing law." Kaucher, 455 F.3d at 423. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.

Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met this burden, the nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id.; Maidenbaum v. Bally's Park Place, Inc., 870 F.Supp. 1254, 1258 (D.N.J.1994). Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the

moving party. Anderson, 477 U.S. at 256-57. "A nonmoving party may not 'rest upon mere allegations, general denials or ... vague statements...'" Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs., 982 F.2d 884, 890 (3d Cir. 1992) (quoting Quiroga v. Hasbro, Inc., 934 F.2d 497, 500 (3d Cir. 1991)). Moreover, the non-moving party must present "more than a scintilla of evidence showing that there is a genuine issue for trial." Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). Indeed, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. Celotex Corp., 477 U.S. at 322.

Moreover, in deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. Credibility determinations are the province of the fact finder. Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

II. Alabama Failure-to-Warn Claim

Plaintiff's theory is relatively straightforward: Defendants failed to adequately warn Plaintiff and his prescribing physicians

of the potential for bleeding complications from taking Plavix. More specifically, Plaintiff insists that his prescribing physicians were not warned regarding Plavix's propensity to cause strokes, heart attacks, abnormal bleeding and "other serious issues and side effects." Am. Compl., ¶ 52. The parties agree that the legal sufficiency of Plaintiff's theory rests on my application of Alabama's learned intermediary doctrine; thus, to that doctrine I now turn.

A. Alabama's Learned Intermediary Doctrine

The Alabama Supreme Court adopted the learned-intermediary doctrine in 1984, in Stone v. Smith, Kline & French Laboratories, 447 So.2d 1301 (Ala. 1984). That case, which addressed whether a manufacturer's duty to warn extends beyond the prescribing physician to the patient who would ultimately consume the drug, was certified to the Alabama Supreme Court by the Eleventh Circuit. See id. Reasoning that physician intermediaries "bridge the gap" between a pharmaceutical manufacturer and a consumer-patient "in cases where the medical product and its related warning are too complex to be fully appreciated by the patient," Morguson v. 3M Co., 857 So.2d 796, 802 n.1 (Ala. 2003)(citing Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1314 (11th Cir. 2000), the Alabama Supreme Court held in Stone that "an adequate warning to the prescribing physician, but not to the ultimate consumer, [is] sufficient as a matter of law" to defeat a failure-to-warn claim in

a prescription drug case. Stone, 447 So.2d at 1303. See Nail v. Publix Super Markets, Inc., 72 So.3d 608, 614 (Ala. 2011) ("The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer and the consumer/patient and, therefore, the physician stands in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment.")[9] Simply put, by virtue of the learned intermediary doctrine, "a manufacturer of prescription drugs discharges its duty [when it] provid[es] the physician with information about risks associated with these products." Bodie v. Purdue Pharma Co., 236 Fed.Appx. 511 (11th Cir. 2007) (quoting Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995) (citation omitted)).

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[9] Plaintiff implores this Court to reject the learned intermediary doctrine when examining Alabama product liability laws. In so doing, Plaintiff relies on a decision rendered by the West Virginia Supreme Court in State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E. 2d 899 (W. Va. 2007), wherein the Court eliminated the learned intermediary doctrine in that state. As Plaintiff should be aware, because Alabama law controls in this case, this Court, sitting in diversity, is bound to follow state law as announced by the highest court in Alabama. See Nuveen Mun. Trust v. Withumsmith Brown, P.C., 692 F.3d 283, 315 (3d Cir. 2012). See also Woodcock v. Mylan, Inc., 661 F.Supp.2d 602, 606 (S.D.Wa. 2009)(in comparing Alabama's learned intermediary doctrine to West Virginia law, noting that the latter "has specifically rejected the learned-intermediary doctrine and continues to hold manufacturers liable for failure to warn."). In this connection, the Court further notes that the few post-Stone Alabama Supreme Court learned intermediary cases do not bear on the questions at issue in this case. Accordingly, I rely upon federal court cases, applying Alabama law, as persuasive authority to inform my conclusion as to how the Alabama Supreme Court would rule.

In Alabama, the learned intermediary doctrine applies with full force to product liability and negligence claims, which claims are governed by the AEMLD. The AEMLD "is a modified version of the strict liability set out in section 402A of the Restatement." See Casrell v. Altec Indus., 335 So.2d 128 (Ala. 1976); Atkins v. Am. Motors Corp., 335 So.2d 134, 137, 140 (Ala. 1976). See also In Re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation, 870 F.Supp.2d 587, 594 (S.D.Ill. 2012) (discussing Alabama law).

> The primary difference between the AEMLD and section 402A is that, unlike section 402A, the AEMLD does not impose a "no-fault" or strict liability concept. Casrell, 335 So.2d at 132. Instead, it "adhere[s] to the tort concept of fault." Id. See also Atkins, 335 So.2d at 137, 140. Thus, to recover under the AEMLD, it is not enough to simply show that a plaintiff took a drug and suffered a resultant injury. Instead, the plaintiff must show "fault" on the part of the manufacturer, supplier, or retailer. Atkins v. Am. Motors Corp., 335 So.2d 134, 139–140 (Ala. 1976).

Yasmin, 870 F.Supp.2d at 594. Fault is established in an AEMLD failure to warn action by showing that the defendant-manufacturer failed to provide adequate warnings of the drug's hazards. Stone, supra at 1303-04; Brasher v. Sandoz Pharmaceuticals Corp., Civil Action Nos. CV–98–TMP–2648–S, CV–98–TMP–2650–S, 2001 WL 36403362, *12 (N.D.Ala. Sept. 21, 2001).

Importantly, "the learned intermediary doctrine may have the effect of destroying the causal link between the allegedly

defective product, and the plaintiff's claimed injury." Id. (internal quotation marks omitted). This is because

> the failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated.

Christopher, 53 F.3d at 1192 (emphasis added). In order words, "the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." Id. Because the plaintiff bears the burden of demonstrating proximate cause, Morguson, 857 So.2d at 796, a plaintiff's failure to present sufficient evidence of causation is fatal to his claim.[10]

B. Adequacy of Warning Label

Plaintiff argues that the Plavix warning label was inadequate because it did not disclose the MATCH study, which study Plaintiff contends illustrates that no benefit is gained from prescribing combination aspirin/Plavix therapy to post-CABG patients. The

[10] A plaintiff asserting a failure-to-warn claim under the AEMLD, must also demonstrate the other elements of a negligence claim: (1) that the defendant had a duty to warn; (2) that the defendant failed to provide adequate warnings of the hazards of a particular product, thereby breaching that duty; and (3) that the plaintiff suffered injury as a result. Bodie, 236 Fed.Appx. at 518 (citing Toole, 235 F.3d at 1314). My analysis, however, focuses largely on causation.

Physician's Desk Reference in effect when Plaintiff was prescribed Plavix provided that Plavix is indicated for "patients with acute coronary syndrome\unstable angina\non-q-wave MI including patients who are to be managed medically, and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG." Watson Cert., Exh. C at 1067. Plaintiff further contends that the warning label should have revealed that Plavix is ineffective for non-smokers. In support of this latter contention, Plaintiff relies upon the testimony of Dr. Moye, Plaintiff's warning label expert.

As I explained in my decision in Solomon, Slip Op. at 20, the MATCH study pertains specifically to patients who have suffered an ischemic stroke or transient ischemic attack; Plaintiff here suffered no such stroke prior to being prescribed Plavix. See Pinson Dep. 167:1-25 (stating that MATCH study relates to stroke patients and suggesting that such a study is not relevant to coronary disease patients); see also id. 94:24-95:3 (distinguishing an ischemic stroke from a hemorrhagic stroke). For this reason, I am skeptical of Plaintiff's suggestion that a post-CABG warning is warranted in this case.

With respect to Plaintiff's reliance on Dr. Moye's opinion about Plavix's effectiveness on non-smoker patients, I explained in Solomon that his expert report does not conclusively demonstrate that Plavix is ineffective on non-smokers. Slip Op. at 21-22.

Rather, Dr. Moye's report states that the effect of Plavix "in nonsmokers depends on the circumstances. In those indications where Plavix has a demonstrable effect, the effect in nonsmokers is also non-negative. However, in patients in whom Plavix is relatively non-effective, representing most of the patient population, Plavix remains ineffective in smokers." Dr. Moye's Report, p. 46. Hence I question whether a non-smoker warning should be required in this case.[11] That said, I need not expressly rule upon whether the 2004 Plavix warning label was adequate because, even assuming its inadequacy, it is clear as a matter of law that Plaintiff cannot demonstrate proximate causation.[12]

C. Proximate Cause

In determining whether a plaintiff has demonstrated proximate cause, courts applying Alabama law look carefully at the testimony of the prescribing physician. If the physician "'had independent knowledge of the risk[s] that the adequate warning should have

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[11] Plaintiff references other potential warnings in the fact section of his brief, e.g.,that a specific warning should be included for patients over 75 years of age, however, he does not link those potential warnings to his personal circumstances. To the extent that Plaintiff seeks to argue that those potential warnings are relevant to him, I reject such a contention for the same reasons expressed in Solomon, Slip Op. at 14-16.

[12] Faced with similarly questionable inadequacy of warning arguments, courts applying Alabama law have assumed for the sake of argument that a challenged warning was inadequate and ruled on causation grounds. See, e.g., Bodie, 236 Fed.Appx. at 519; Trasylol Prod. Liab. Litig.- MDL - 1928, Civil Action No. 08-MD-1928, 2011 WL 2117257 (S.D.Fla. 2011); Barnhill v,. Teva Pharm. USA, Inc., 81`9 F.Supp.2d 1254 (S.D.Ala. 2011).

communicated,' and chose to prescribe the drug based on that independent knowledge, then, by law, the allegedly inadequate warning of the drug company is not the proximate cause of the plaintiff's injury." Bodie, 236 Fed.Appx. at 521 (quoting Christopher, 53 F.3d at 1192). In other words, if the physician was already aware of the risks that the plaintiff contends should have been included in the warning, and/or the physician made the decision to prescribe without reference to the manufacturer's literature, the plaintiff's claim necessarily fails. See id. at 521-22; id. at 522 n.12 ("The question, for purposes of Bodie's negligent failure to warn action, is whether Dr. Mangieri's decision to prescribe OxyContin to Bodie ultimately hinged on the information (accurate or inaccurate) that he obtained from Purdue."); Tatum v. Schering Corp., 795 F.2d 925 (11th Cir. 1986) ("It all returns therefore to the critical inquiry of what Dr. Karst knew ...."). Moreover, where a physician testifies that nothing in the manufacturer warning label could cause him to change his decision to prescribe, causation is not shown. See Tatum, 795 F.2d at 928 (noting that independent knowledge was shown when physician "testified . . . that there is no known, universally accepted treatment for aplastic anemia, and that nothing in the information sheet or in any other source could cause him to change his belief.")

Conversely, a plaintiff may demonstrate proximate cause by showing that the new warning would have changed the physician's calculation of the risks and benefits of the drug and caused the physician not to prescribe the drug.[13] See Brasher, 2001 WL 36403362 at *13. Alternatively, where the new warning would not have caused the physician to alter his prescribing habits, a plaintiff may demonstrate proximate cause by showing that the new warning would have at least "changed [the physician's] . . . treatment in some way that would have resulted in a different outcome for [the] Plaintiff." Barhill, 819 F.Supp.2d at 1261; see also Toole, 999 F.2d at 1433 (denying summary judgment on proximate cause grounds where physician testified that had he known "in 1981 that there was a-even a slightly significant instance of rupture of the implants, then I would have . . . warned my patient.") (emphasis added). However, where a physician testifies that he or she continues to prescribe the medicine despite now having full knowledge of the risks that would have been included in the new warning, courts applying Alabama law have held that the

[13] In this connection, I note that courts applying Alabama law further require a plaintiff to show that his proposed new warning would have been "read and heeded" by the physician. McClain v. Roddy Coca Cola Bottling Co., Civil Action No. 08-614, 2009 U.S. Dist. LEXIS 85045, *19-20 (N.D.Ala. 2009)(discussing Gurley v. Amer. Hondo Motor Co., 505 So.2d 358, 361 (Ala. 1987)). See also Barhill, 819 F.Supp.2d at 1261. Because the parties do not focus upon this issue in their briefs, and because I ultimately conclude that Plaintiff cannot demonstrate proximate cause in light of his treating physicians' deposition testimony, I do not address the "read and heed" requirement under Alabama law.

plaintiff has failed to demonstrate proximate cause. See, e.g., Bodie, 236 Fed.Appx. at 521; Trasylol, 2011 WL 2117257 at *5; Barhill, 819 F.Supp.2d at 1262.

As an initial matter, I note that the parties discuss testimony from Plaintiff's cardiac surgeon, Dr. Johnson, who did not prescribe Plavix to Plaintiff. His testimony is not relevant because, while he performed Plaintiff's surgery, he had no role in prescribing the drug. See Johnson Dep. 77:7-21. Indeed, the facts of this case are unique in that the record does not reveal the name of the doctor who initially prescribed Plavix to Plaintiff. Furthermore, the parties discuss the testimony of Dr. Pinson, the physician who oversaw Plaintiff's post-surgical care while in Flowers Hospital immediately following Plaintiff's cardiac surgery. Dr. Pinson concurred with the decision of the unknown doctor who initially prescribed Plavix to Plaintiff. He, further, monitored Plaintiff on a periodic basis after he was discharged. During that period of monitoring, however, Plaintiff's continued Plavix prescription was written by his primary physician—Dr. Williams–and Dr. Pinson did not alter that prescription. See Pinson Dep. 73:20-75:14 (clarifying that he did not prescribe Plavix); id. at 128:10-130:17 (noting that he concurred with the initial decision to place Plaintiff on Plavix); id. at 170-176 (describing follow-up visits). While I will briefly address Dr. Pinson's testimony in my analysis, his testimony, however, is of limited relevance because he did not

initially prescribe the drug or authorize refill prescriptions. Thus, the bulk of my analysis will center on the testimony of Dr. Williams.[14] Accord See also Earl v. Eli Lilly & Co., 688 F.Supp.2d 130, 148 (E.D.N.Y. 2009) (in applying Alabama law, focusing on the knowledge of the doctor who authorized refill prescriptions over a period of several years where there was "no evidence about the knowledge of the physicians or medical team responsible for the initial decisions to prescribe ....").

As noted, Plaintiff underwent a left heart cardiac catheterization and bypass surgery in September 2004. While at the hospital, he was seen by Dr. Pinson and, once he was discharged, by his primary care physician, Dr. Williams, for follow-up care. Dr. Williams continued Plaintiff's prescription for Plavix/aspirin combination therapy for several months following the surgery until the cerebellar hemorrhage incident in February 2005.

In arguing that he has demonstrated causation, Plaintiff points to Dr. Williams' testimony that, in deciding whether to prescribe an anticoagulant like Plavix, "it would be important" to

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[14] In this connection, I note that Plaintiff also points to his own testimony and that of a pharmaceutical sales representative in support of his claims. This testimony is not relevant to my proximate cause analysis; it is the testimony of the prescribing physician around which my proximate cause analysis must center. Cf. Toole, 999 F.2d at 1433 ("Under the learned intermediary doctrine, the adequacy of Baxter's warning is measured by its effect on the physician, Dr. McClintock, to whom it owed a duty to warn, and not by its effect on [the plaintiff-patient].") (internal quotation marks omitted).

him to know if there was a study indicating that "there is no benefit seen for [Plavix] use after CABG." Id. at 161:21-162:6. In Plaintiff's view, this testimony establishes that Dr. Williams would have "changed [his] behavior or treatment in some way that would have resulted in a different outcome for [the] Plaintiff." Barhill, 819 F.Supp.2d at 1261. However, when read in context, Dr. Williams states that he would consider that information "along with the universe of data that is available on the medication." Id. at 162:4-6.

But even assuming that Dr. Williams would have considered it important to be apprised of the MATCH study findings, Plaintiff has failed to point to any evidence demonstrating that Dr. Williams would have altered his prescribing or treatment habits. There are several excerpts from Dr. Williams' testimony that make this clear. Most notably, Dr. Williams testified at his deposition that, having heard Plaintiff's summary of the MATCH study findings and Plaintiff's other contentions that the medicine is ineffective, he nonetheless would not have altered his decision to continue Plaintiff's prescription:

> Q: . . . Doctor, have you seen or heard anything today to change what you told me earlier, which is that you thought that Plavix and aspirin were appropriate for Mr. Cooper back in October of 2004?
>
> A: I felt that they were appropriate medications at that time and, if that situation were recreated again today, I would give him the same medications.

Id. at 172:11-19 (emphasis added).

Moreover, Dr. Williams' testimony confirms that he was fully aware of the bleeding risks attendant to Plavix use:

> Q: What would have been the potential risks to Mr. Cooper of not prescribing Plavix and aspirin to him at that point?
>
> A: I believe that [Plaintiff] would have been at increased risk of a heart attack or angina or the types of manifestations of coronary artery disease without giving him anticoagulation and in particular aspirin and Plavix.
>
> Q: And were you aware at that point when you wrote the prescription that one of the potential risks of a Plavix and aspirin prescription was a risk of some bleeding complications?
>
> A: Yes, I was.
>
> Q: And was it your view at that point that the benefit -- potential benefits to Mr. Cooper of that combination exceeded the potential risks of bleeding?
>
> A: In my view at that time, the risk-and-benefit ratio to him favored his continuation of aspirin and Plavix.
>
> Q: What kind of bleeding risks are present with that combination, Plavix and aspirin?
>
> A: Any type of bleeding risk would be possible with those types of medications. One can bleed from any blood vessel in your body at any time, and the use of aspirin and Plavix or the other anticoagulants that we've talked about earlier increases the risk potentially of bleeding from any site.

Id. at 113:19 - 114:24.

This testimony, coupled with Dr. Williams testimony that he would prescribe Plavix to Plaintiff again even with the benefit of the additional post-CABG warning proposed by Plaintiff, undercuts Plaintiff's argument that Dr. Williams would have altered his prescribing or treating habits. Moreover, with respect to the

effectiveness of Plavix on non-smokers, Plaintiff has not pointed to record evidence demonstrating that Dr. Williams would have altered his prescribing or treatment habits upon being informed of such a lack of efficacy. Compare Lilly, 688 F.Supp.2d at 149 (denying summary judgment where doctor testified that "had I known that [the drug] had a significantly greater risk of weight gain, insulin resistance, and diabetes, than had been revealed by [the drug manufacturer], I would have pursued other options for the treatment of [the plaintiff-patient's] symptoms."); Levine v. Wyeth, Inc., Civil Action No. 8:09–cv–854–T–33AEP, 2010 WL 5137424, *6 (M.D.Fla. 2010)[15] (denying summary judgment where doctor testified that "had he known of the risk of developing tardive dyskinesia set forth in the 2009 version of the warning, he would have warned Plaintiff to be more cognizant of the possibility of developing tardive dyskinesia and to use Reglan with caution.")

With respect to Dr. Pinson, his testimony demonstrates that he was fully aware of the risks of dual therapy. He testified:

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[15] Although this Middle District of Florida case applied Florida law, it based its decision, in part, on the Alabama law ruling in Toole, supra, while noting the similarity between Alabama's and Florida's learned intermediary doctrine. See id. ("[T]his Court finds Toole to be persuasive since both Florida and Alabama apply the learned intermediary doctrine when analyzing a failure to warn claim against a manufacturer of a prescription drug or device. Both the Florida Supreme Court and the Alabama Supreme Court rely on the Fifth Circuit case of Reyes v. Wyeth Laboratories when explaining the learned intermediary doctrine.") (internal citations omitted).

Q: You were aware at the time, in September of 2004, that there was a bleeding risk associated with using antiplatelet drugs; is that -- is that right?

A: Inherently, there's an increased bleeding risk when you're on some form of antiplatelet or anticoagulant therapy.

* * *

Q: And was it also -- did you also understand at the time that using two of those together -- in this case, Plavix and aspirin -- might increase the bleeding risk over using one or the other alone?

A: That would be intuitive, in addition to the information available .... Obviously, if you combine the effect of the drugs, it has a more potent effect in terms of bleeding, risk of bleeding.

Id. at 113:19 - 114:24. The reason he concurred with the prescribing physician's decision to place Plaintiff on Plavix, despite the increased risk of bleeding attendant to dual therapy, was the severity of Plaintiff's cardiac condition– his graft closure and clotting and severe diffuse coronary disease. See id. at 135:21-25; 207:2-14. Most importantly, like Dr. Williams, Dr. Pinson testified that nothing he heard from Plaintiff at his deposition, including the MATCH study findings and Plaintiff's other efficacy concerns, would have altered his opinion on the propriety of the Plavix prescription. See id. at 207:2-208:12.

In reviewing Dr. Williams' entire deposition, his testimony makes clear that the additional warning language would have had no effect on the doctor's decision to prescribe. Dr. Williams was aware of the risks that Plavix posed, yet he concluded that the

benefits of the combination Plavix/aspirin therapy outweighed the risks of bleeding. Even with the benefit of the additional proposed warning language, he would again prescribe Plavix to Plaintiff under similar circumstances to that present in 2004. The same holds true for Dr. Pinson, who also reaffirmed his concurrence with Plaintiff's initial Plavix prescription. Accordingly, Plaintiff's failure to warn claim cannot withstand summary judgment on proximate cause grounds. Accord Bodie, 236 Fed.Appx. at 521; Trasylol, 2011 WL 2117257 at *5; Barhill, 819 F.Supp.2d at 1262.

Urging a different result, Plaintiff argues that proximate cause is a question for the jury. While proximate cause should be presented to a jury where a genuine issue of material fact exists, as noted, courts have not hesitated to grant summary judgment on proximate cause grounds where the proposed warning would not have changed the prescribing physician's decision to prescribe. See, e.g., Bodie, 236 Fed.Appx. at 521; Barnhill, 819 F.Supp.2d at 1262. In this regard, the Fifth Circuit has explained, "determining that a party has failed to establish an essential element of the claim is a proper consideration on summary judgment and is not a finding of fact to be left to the jury." Ebel v. Eli Lilly & Co., 321 Fed. Appx. 350, 357 (5th Cir. 2009). Cf. McClain, supra at *19 ("a . . . failure-to-warn adequately case should not be submitted to the jury unless there is evidence that an adequate warning would have

. . . prevented the alleged accident."[16]) Accordingly, summary judgment is granted on Plaintiff's failure to warn claim based on application of the learned intermediary doctrine.

III. Alabama Defective Design Claim

Plaintiff's design defect claim is premised on Defendants' alleged failure to warn. See Opp. Br. at 37 ("Because there were not proper instructions on the Plavix label, because the label was not properly prepared, and because the benefits of Plavix do not outweigh the risks, the Plaintiff can proceed on a defective design claim under the AEMLD.") Indeed, under Alabama law, only those drugs that are "not accompanied by ethical warnings" may form the basis of a defective design claim. Stone, 447 So. 2d at 1304 ("[I]n the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous.") See also Emody v. Medtronic, Inc., 238 F.Supp.2d 1291, 1296 (N.D. Ala. 2003) ("[U]nder [the] AEMLD, prescription[s] are unavoidably unsafe products, and where inherent risks are at issue, the only other permissible theory of liability is inadequate warning.") (citing Stone, supra at 1301). While

[16] Plaintiff further urges the Court to apply a presumption of causation as discussed in Lemmon v. Wyeth, LLC, Civil Action No. 04-1302 (ERW), 2012 WL 2848161 (E.D.Mo. Jul. 11, 2012), a Missouri district court decision applying Missouri law. Id. (citing Grady v. Am. Optical Corp., 702 S.W.2d 911, 918 (Mo.App. 1985)). Needless to say, this Court may not rely upon a Missouri case to predict Alabama law.

Plaintiff seeks a different result by citing to law from other jurisdictions discussing the Restatement 2d of Torts, § 402A, comment K, as noted, Alabama deviates from the Restatement and is among the "minority of courts [that] have interpreted comment k more broadly and provide all prescription drugs categorical immunity from strict liability for design defects." Moss v. Wyeth, Inc., --- F.Supp.2d ---, 2012 WL 1899876, *4 (D.Conn. 2012). Therefore, having already determined that Plaintiff is unable to establish any triable issue with respect to his failure-to-warn claim, Plaintiff's design claim correspondingly fails.

IV. Alabama Manufacturing Defect Claim

Like with design defect claims under the AEMLD, manufacturing defect claims relating to prescription drugs may be premised only upon a failure to warn. Hence, as Plaintiff's failure to warn claim does not withstand summary judgment, neither does his manufacturing defect claim. Accord Emody, 238 F.Supp.2d at 1296 (granting summary judgment on manufacturing defect claim where learned intermediary rule barred failure to warn claim).

V. Negligence Claim

Plaintiff's negligence claim is nothing more than a restatement of his defective design, defective manufacturing, and failure-to-warn claims. Plaintiff avers that Defendants negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold

Plavix. See Am. Comp., ¶¶ 69-71. Because the Court has found that none of his claims have merit, this claim necessarily fails.

VI. Discovery Request Pursuant to Rule 56(d)

As a final note, Plaintiff seeks additional discovery pursuant to Fed. R. Civ. P. 56(d). Based on the Court's ruling herein, there is no basis to provide Plaintiff additional opportunities to seek discovery. Moreover, much of what Plaintiff proposes to discover relates to Plavix's effectiveness, which, for the reasons explained in my opinion in Solomon, supra, is neither relevant nor probative of Plaintiff's claims. Also, Plaintiff has had the opportunity to take the depositions of Plaintiff's treating physicians. As the Court has already found that the physicians' testimonies do not support Plaintiff's claim in light of the learned intermediary doctrine, additional discovery would not lead Plaintiff to any new evidence that would change the results here. Accordingly, Plaintiff's position that the motion is premature and further discovery should be taken is rejected.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in its entirety. As a result, Plaintiff's Amended Complaint is dismissed.

An appropriate Order shall issue.

Dated: January 4, 2013

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge